

HUBERT DORN ET AL.
USSN 09/780,646

ADDITIONAL FEE

Please charge any insufficiency of fees, or credit any excess, to Deposit Account No. 14-1263.

REMARKS

Applicants respectfully request reconsideration and allowance of this application in view of the following comments.

The sole issue for consideration is the rejection of claims 10-15 under 35 USC § 103(a) as being obvious over European Patent Application No. 0 285 985 ("EP-A-0 285 985") and European Patent Application No. 0 259 738 ("EP-A-0 259 738"). In response, Applicants respectfully request that the Examiner reconsider and withdraw this rejection.

Before discussing the cited references in detail, Applicants note that the Examiner takes the position that "the prior art clearly teaches that the claim designated * * * compounds * * * may be applied in *a non-systemic control method such as dermal application.*" In response, Applicants have already pointed out that "dermal" is not synonymous with "non-systemic." Consequently, the fact that a reference teaches dermal application does not mean that the reference inherently teaches non-systemic control.

It is well known in the art that many active substances, albeit they are dermally applied, may penetrate the skin, enter the bloodstream and be distributed throughout the body in a

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systemic manner. Thus, simply because a reference teaches dermal application does not necessarily mean that the application is also non-systemic.

The Examiner has not established the well known state of the prior art to be other than Applicants have set forth in the preceding paragraph. Therefore, the present rejection cannot be maintained simply by showing that the cited prior art mentions dermal application. Instead, the Examiner must show that the prior art teaches or suggests non-systemic application specifically. Applicants submit that the cited references nowhere teach or suggest non-systemic application specifically. Consequently, the Examiner should reconsider and withdraw this rejection.

To the best of Applicants' knowledge, at the time the present invention was made, persons skilled in the art would not have considered the non-systemic application of the compounds of the present claims in order to control ectoparasitic insects on animals or humans. Such persons also would not have expected their surprisingly high efficiency over a long term. While referring to a different type of compounds, but of the same class of agonists or antagonists of the nicotinerbic acetylcholine receptors of insects, the introductory part of WO 93/24002, of record here, accurately reflects the thinking of persons skilled in the art at the time the present invention was made. Although dermal application of active ingredients to animals was, of course, known in general principle, WO 93/24002 discloses that only systemic application is suitable for the compounds disclosed therein. Thus, non-systemic application was clearly thought to be unsuitable for compounds such as are described in WO 93/24002.

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The same expectation applied to the specific compounds required by the instant claims. The prevailing thought was that systemic application must be achieved, even if the application was a dermal application. Nothing in the cited references suggests otherwise.

EP-A-0 285 985 lists virtually all known application forms for veterinary medicine. See page 7, lines 31 ff, of the German text. However, as all of these application forms are listed without specific comments or preferences, the document does not surmount the prejudice in the art that systemic application must be achieved. Consequently, the reference would not have led persons skilled in the art to carry out dermal application in such a way as to achieve non-systemic application, as presently claimed.

In further support of Applicants' position, there is attached a partial translation of the paragraphs of EP-A-0 285 985 upon which the Examiner relies. Although the reference does mention dermal application, the reference is silent as to the achievement of non-systemic control. Consequently, EP-A-0 285 985 would not, in fact, have suggested non-systemic application to persons skilled in the art.

With respect to EP-A-0 259 738, the Examiner points to page 9, lines 35-42. However, Applicants again point out that in line 36, the reference discloses that the compounds are active against *endoparasites*, such as worms. Although the reference also teaches usefulness against ectoparasites, the reference does not make a distinction between the methods to be used to treat endoparasites and those to be used to treat ectoparasites, and, thus, a person having ordinary skill in the art would have been led to the conclusion that the two methods are the same. Obviously,

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endoparasites, because they are inside of the host animal, must be treated by a method that brings the active compound into the body of the host animal, which method is necessarily a systemic method. Ectoparasites could also have been treated by the same systemic method. Consequently, EP-A-0 259 738 also would not have suggested non-systemic application to persons skilled in the art.

To the extent that non-systemic dermal application is considered to be an obvious choice of administration method, Applicants would request that the Examiner reconsider the data of record. The data show that the results achieved with non-systemic dermal application are superior even to those obtained with oral treatment. There is absolutely nothing in the cited prior art that teaches or suggests the superiority of non-systemic dermal application over oral treatment. Consequently, the data in the declarations of record are proof of a surprising and unexpected result, which is, thus, objective evidence of nonobviousness.

In view of the foregoing, Applicants respectfully request that the Examiner reconsider and withdraw this rejection. An early notice that this rejection has been reconsidered and withdrawn is earnestly solicited.

Applicants believe that the foregoing constitutes a bona fide response to all outstanding objections and rejections.

Applicants also believe that this application is in condition for immediate allowance. However, should any issue(s) of a minor nature remain, the Examiner is respectfully requested to

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telephone the undersigned at telephone number (212) 808-0700 so that the issue(s) might be promptly resolved.

Early and favorable action is earnestly solicited.

Respectfully submitted,

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By

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CERTIFICATE OF FACSIMILE TRANSMISSION

I hereby certify that the foregoing Amendment under 37 CFR § 1.116 and the accompanying Request for Continued Examination (RCE), Partial Translation of European Patent No. 0 285 985, PTO Form 1449 listing the partial translation of European Patent No. 0 285 985, and Petition for Extension of Time (10 pages total) are being facsimile transmitted to the United States Patent and Trademark Office on the date indicated below:

Date: March 10, 2003

By

Kurt G. Briscoe

0 285 985

(...)

Application of the invented active ingredients occurs in the veterinary sector in the convention fashion through enteral administration in the form of tablets, capsules, impregnation, drenching, granules, pastes, boli, the feed-through method, suppositories, through parenteral administration such as through injections (intramuscular, subcutaneous, intravenous, intraperitoneal etc.), implants, through nasal application, through dermal application in the form of immersion or bathing (dipping), spraying (spray), pouring (pour-on and spot-on), rinsing, powdering as well as with the help of molded bodies such as collars, ear marks, tail marks, joint marks, head-collars, marking devices etc.

The active ingredients can be transferred into conventional formulations in dependency upon their respective physical and/or chemical properties, e.g. solutions, emulsions, suspensions, powders, foams, pastes, granules, aerosols, active ingredient impregnated natural and synthetic substances, micro-encapsulations in polymer substances and in pelleting substances for seeds, furthermore formulations with combustibles, such as smoke cartridges, can, spirals and the like, as well as ULV cold and warm fog formulations.

(...)

PARTIAL TRANSLATION OF
EP-A-0 285 985 FOR
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